



## REMARKS

Applicants have amended claims 1 and 11-13 and have added new claims 17-19. The Examiner's comments and rejections are addressed below in the order in which they were presented.

### The 35 U.S.C. § 102(e) Rejections

The Examiner has rejected claims 1-8, 10-14 and 16 under 35 U.S.C. § 102(e) as being anticipated by Masuo (U.S. Patent No. 6,321,112 B1). Applicant respectfully traverses this rejection.

Masuo is directed to a device for measuring the impedance across a body portion by applying a fixed current using one pair of electrodes and measuring the impedance using a second pair of electrodes, each positioned respectively near the first set of electrodes. *See* col. 2, lines 52-57. The fixed current is supplied by the device itself, as shown by the current supply symbols in Fig. 4, elements 21a and 21b. More specifically, Masuo teaches applying a fixed high frequency current signal to a first pair of electrodes in contact with the body (e.g., a hand and a foot), thereby passing the current between these electrodes and through the body. The voltage related to this fixed high frequency current is then measured using a second set of electrodes respectively placed near the first set of electrodes. From the known value of the fixed high frequency current and the measured value of the voltage related to this fixed high frequency current, the body impedance is calculated.

Basically, Masuo teaches the use of an impedance meter to measure the impedance associated with an applied current through the body. Masuo requires a total of at least 4 electrodes, the generation of a fixed high frequency current, which is passed through the body, and the measurement of the impedance experienced by this current. Effective operation of the device taught by Masuo is dependent on exclusively measuring the voltage generated from the current supplied by the device itself. External environmental currents and voltages are a source of noise and error to the device of Masuo. These environmental currents and voltages are avoided by using tightly controlled, high frequency, high amplitude current sources generated by the device itself, wherein the frequencies used are uncommon in the external environment.

The present invention, as recited in independent claim 1, is directed to an apparatus for measuring the current flow through a body comprising data acquisition circuitry

consisting essentially of a first contact and a second contact to generate voltage data.

Applicants point out that the data acquisition circuitry as recited in claim 1 consists essentially of two contacts and related connectors and, therefore is not anticipated by the device taught by Masuo, which requires at least 4 electrodes for operation as taught by Masuo.

Additionally, claim 1 recites a portable data processing unit to process voltage data generated by the data acquisition circuitry to produce current flow data. This current flow data is a measurement of the current flow produced in the body by its environs, or that is naturally traveling through the body, since in the present invention there is no artificially and separately applied current as there is in Masuo. In other words, the portable data processing unit of claim 1 processes the voltage data collected by the data acquisition circuitry in conjunction with body impedance data to produce current flow data, which again is the actual current flow through the body under normal or natural conditions. The device taught by Masuo, on the other hand, produces impedance data from a measured voltage associated with an artificially applied and known high frequency current. Masuo simply does not teach or suggest a data processing unit to process voltage data and body impedance data to produce the type of current flow data recited in claim 1.

Further, Masuo does not teach body impedance data as recited in claim 1. The body impedance data recited in claim 1 is that which is used by the data processing unit in connection with the measured voltage data to produce the current flow data. It is not necessary to measure both impedance and voltage simultaneously to determine the current flow data. In one embodiment, the body impedance data comprises generic body impedance data from previously conducted studies that are stored in the memory of the apparatus. Using Ohm's law, the current flow data can be calculated using the voltage data and the body impedance data. However, other sources of body impedance data may be used.

The only impedance data measured by the device in Masuo, or taught by Masuo, is that which is determined in connection with the application of a high frequency current through the body, which is on the order of kHz. The frequency of the natural current flow through the body, however, is orders of magnitude less. Therefore, even assuming, *arguendo*, that the device taught by Masuo could be used to measure the voltage associated with the natural current flow in a body, the calculation of the natural current flow would be based upon impedance data measured at an inappropriate frequency. Therefore, the current

flow data would not be accurate. Applicants reiterate, however, that Masuo does not teach or suggest only the use of two contact to measure such voltage associated with the background or natural current, as at least 4 electrodes are required for proper operation of the device taught by Masuo. Moreover, the device taught by Masuo uses an amplifier that is tuned to the frequency of the applied current sources and measures the voltage created by these sources, as opposed to being tuned to the frequency of the current measured by the present invention.

Based on the foregoing, Masuo does not anticipate each and every element of independent claim 1, nor the claims dependent therefrom, and withdrawal of this rejection is respectfully requested.

In connection with the rejection of Claims 11 and 12, the Examiner cites to col. 11, lines 53-55 and to col. 12, lines 41-46 as Masuo teaching a memory that stores body impedance data comprised of known body impedances and as these known body impedances being estimated, respectively. The only body impedance data that Masuo refers to is that which is measured by the device itself. The “known body impedances” recited in Claims 11 and 12 are not measured by the device itself. In one embodiment, these known body impedances are previously known from other studies and are stored in the memory of the apparatus for use in calculating the current flow from the measured voltage data. (*See* Specification, page 5, lines 7-12.) In the citations made by the Examiner, Masuo teaches that the measured impedance is checked to determine whether it is a stable reading and in the correct range. However, Masuo does not teach a memory that stores known body impedance data from other sources as recited in Claims 11 and 12. Therefore, withdrawal of this rejection is respectfully requested.

With respect to new independent Claim 17, this apparatus also recites a memory that stores “generic body impedance data” for use in determining the current flow through the body. Again, Masuo does not teach the use of such generic body impedance data and only teaches the use of the impedance data actually measured by his device. Therefore, it is believed that this new independent claim and the claims dependent therefrom are allowable.

### **The 35 U.S.C. § 103 Rejections**

The Examiner has rejected Claims 9 and 15 under 35 U.S.C. § 103(a) as being obvious over Masuo in light of Fukuda *et al* (U.S. Patent No. 6,393,317). The Examiner has

also rejected Claim 16, in the alternative to the rejection under 35 U.S.C. § 102, as being obvious over Masuo in view of Masuo *et al* (U.S. Patent No. 5,817,031). In light of the arguments made above and the amendments to the claims, Applicants submit that these rejections are now moot and respectfully request withdraw of these rejections.

### **Conclusion**

Attached hereto is a marked-up version of the changes made to the claims by the current amendment. This attached page is captioned "Version With Markings to Show Changes Made."

In view of the above considerations, Applicants respectfully request a timely Notice of Allowance in this application. Applicants believe that no fee is due with this submission. However, if it is determined that a fee is due, please charge the required fee to Pennie & Edmonds LLP Deposit Account No. 16-1150. A copy of this sheet is enclosed.

Respectfully submitted,



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**VERSION WITH MARKINGS TO SHOW CHANGES MADE**

**In the Claims:**

Claims 1 and 11-13 have been amended as follows:

1. (Amended Once) An apparatus for measuring current flow through a living body, comprising:

data acquisition circuitry consisting essentially of a first contact and a second contact to generate voltage data and a first connection connected at a first end to said first contact and a second connection connected at a first end to said second contact; and

a portable data processing unit connected to a second end of said first connection and to a second end of said second connection [said data acquisition circuitry] to process said voltage data and body impedance data to produce current flow data.

11. (Amended Once) The apparatus of claim 10 wherein said memory stores said body impedance data comprised of known body impedances.

12. (Amended Once) The [memory] apparatus of claim 11 wherein said known body impedances include estimated impedances.

13. (Amended Once) The [memory] apparatus of claim 11 wherein said known body impedances include calculated impedance measurements.

New claims 17-19 have been added as follows:

17. (New) An apparatus for measuring current flow through a living body, comprising:

data acquisition circuitry comprising a first contact and a second contact configured to generate voltage data from a living body; and

a data processing unit electrically connected to said data acquisition circuitry, wherein said data processing unit comprises a memory configured to store generic body impedance

data and to calculate a current flow through said living body using said voltage data and said generic body impedance data.

18. (New) The apparatus of claim 17, wherein said data processing unit further comprises:

at least two channels electrically connected to said first and second contacts, respectively, wherein each of said channels comprises a low noise filter, a high pass filter, a low pass filter, an adjustable threshold detector and an analog to digital converter;

a system bus electrically connected to said channels;

a central processing unit electrically connected to said system bus; and

wherein said memory is electrically connected to said system bus and comprises a set of executable programs.

19. (New) The apparatus of claim 18, further comprising:

an LCD display electrically connected to said data processing unit;

a removable memory capable of being electrically connected to said data processing unit; and

an autonomous power supply electrically connected to said data processing unit.